

K091679

1083



OCT - 2 2009

**Exhibit 5      510(k) Summary of Safety and Effectiveness**

**Model: LeForte Neuro System Bone Plate**

1.      Submitter and US Official Correspondent

Submitter:                      Jeil Medical Corporation  
Address:                        #702, Kolon Science Valley 2<sup>nd</sup>  
                                      811, Guro-dong, Guro-gu  
                                      Seoul, 152-050, Korea  
  
Official Correspondent:      Shin Kuk Yoo, Consultant  
Telephone No.:                714-313-7442  
Fax No.:                        801-303-7455  
Email:                         [skyone@LSKBioPartners.com](mailto:skyone@LSKBioPartners.com)

2.      Establishment Registration Number

3004049923

3.      Device Information

Proprietary/Trade Name:    LeForte Neuro System Bone Plate  
Common/Usual Name:        Bone Plate  
Classification Name:         Plate, Bone  
Classification Product Code: JEY  
Device Class:                 Class II per regulation 21 CFR 872.4760

4.      New or Modification

The application is intended for premarket notification of new medical device, LeForte Neuro System Bone Plate, for US market.

5.      Equivalent Legally Marketed Device

- 1) Plate, Bone (Model: Synthes (USA) Neuro Plate and Screw System) manufactured by Synthes (USA) – K042365, Decision Date: 11/18/2004, JEY (Class II per regulation 21CFR 872.4760)

K091679

2 of 3

6. Description of the Device

LeFort Neuro System Bone Plate is made of unalloyed titanium (ASTM F67) and is manufactured and intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin. Jeil Medical Corporation utilizes the state of the art technology and apply the essential requirement of MDD(93/42/EEC) and ISO 14630:1997 from the device design to manufacturing and QC.

7. Indications for Use (Intended Use)

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

8. Potential Adverse Affects and Complications (Common to all devices of this type)

- 1) Poor bone formulation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening, bending, cracking or fracture of the device or premature loss of fixation with the bone, leading to nonunion.
- 2) Nonunion or delayed union which may lead to breakage of the implant.
- 3) Migration, bending, fracture or loosening of the implant.
- 4) Metal sensitivity, or allergic reaction to foreign body
- 5) Decrease in bone density due to stress shielding
- 6) Pain, discomfort, or abnormal sensation due to the presence of the device
- 7) Increased fibrous tissue response around the fracture site and/or the implant
- 8) Necrosis of bone
- 9) Inadequate healing

Apart from these adverse effects there are always possible complications of any surgical procedure such as but not limited to, infection, nerve damage and pain which may not be related to the implant.

K09 1679

373

9. Safety and Effectiveness, comparison to Predicate device

Device Name	LeForte Neuro System Bone Plate	Synthes(USA) Neuro Plate & Screw System
Applicant	Jeil Medical Corporation	Synthes(USA)
510(k) Number	New	K042365
Classification	Plate, Bone (Class II, 21 CFR 872. 4760)	Bone Plate (Class II, 21 CFR 872. 4760) Burr hole cover (Class II, 21 CFR 882. 5250) Intraosseous fixation screw or wire (Class II, 21 CFR 872. 4880)
Material	Titanium	Titanium Titanium Alloy
Intended Use	This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.	This device is intended for use in selective trauma of the mid-face and craniofacial Skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.
Single use	Single Use	Single Use
Sterile	Non-sterile	Non-sterile

10. Conclusion

In all respects, the LeForte Neuro System Bone Plates are the equivalent of currently marketed devices. They are made of the same materials and have similar dimensions and characteristics. Potential adverse effects are identical to those of the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Jeil Medical Corporation  
C/O Mr. Shin Kuk Yoo  
Manager  
LSK BioPartners, Incorporated  
215 South State Street, Suite 100B  
Salt Lake City, Utah 84111

**OCT - 2 2009**

Re: K091679

Trade/Device Name: LeForte Neuro System Bone Plate (Various Models)  
Regulation Number: 21 CFR 872.4760  
Regulation Name: Bone Plate  
Regulatory Class: II  
Product Code: JEY  
Dated: September 8, 2009  
Received: September 10, 2009

Dear Mr. Yoo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

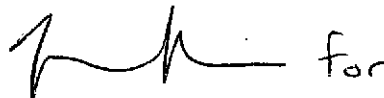
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", followed by the word "for" in a cursive script.

Susan Runner, D.D.S., M.A.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K091679

1081

**Exhibit 4 Indications for Use**

510(k) number (if known): \_\_\_\_\_

Device Name: LeForte Neuro System Bone Plate (Various Models)

Indications for Use:

This device is intended for use in selective trauma of the mid-face and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin.

Prescription Use ☒ AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey Son MDR  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K091679